I. COVID-19 LEGAL UPDATES

Brach Eichler has strived to keep abreast of the numerous legal developments that are related to the nationwide novel coronavirus (COVID-19) public health emergency. Brach Eichler has created a COVID-19 Resource Center that consolidates our various important client alerts and webinar series information in one place. Please visit the Resource Center for updates at https://www.bracheichler.com/covid-19-resource-center/.

II. NEW JERSEY DEVELOPMENTS

A. Governor Murphy Signs Executive Orders Reinstating the COVID-19 Public Health Emergency and Extending Several Executive Orders

On January 11, 2022, Governor Murphy reinstated the COVID-19 Public Health Emergency (PHE) by signing Executive Order (EO) 280. Immediately following the signing of the EO 280, Governor Murphy signed EO 281, which reinstates a couple of EOs that has been expired and extends the effectiveness of several other EOs.

Notable EOs that have been reinstated are listed below:

- EO No. 111: Directing health care facilities to report their capacity and supplies, including bed capacity ventilators, and PPE inventory on a daily basis.
- EO No. 112: Granting the Department of Law and Public Safety, Division of Consumer Affairs, the authority to temporarily reactivate certain inactive health care licenses and allow the licensure of physicians licensed, and in good standing, in another country; suspended and waived certain licensure requirements for advanced practice nurses and physician assistants; relaxed registration requirements for the Prescription Monitoring Program; waived signature requirements for funeral agreements and authorizations; and provided certain healthcare professionals with civil or criminal immunity.

In addition, the following EO now remains in full force and effect:
• EO No. 252: Requiring all covered health care and high-risk congregate settings to maintain a policy that requires all covered workers to either provide adequate proof that they have been fully vaccinated or submit to COVID-19 testing at minimum one to two times weekly beginning September 7, 2021.

The PHE will allow the State to continue vaccine distribution, vaccination or testing requirements in certain settings, the collection of COVID-19 data, implementation of any applicable recommendations of the Centers for Disease Control and Prevention to prevent or limit the transmission of COVID-19, staffing and resource allocation, and other components of the State's COVID-19 response.

B. New Law Revises Requirements for Insurers to Cover Telemedicine Services

On December 21, 2021, Governor Murphy signed into law former Bill S2559, which requires that health benefits plans reimburse health care providers for telehealth and telemedicine services at the same rate as in-person services. Additionally, carriers offering health benefit plans in New Jersey, the State Medicaid and NJ FamilyCare programs, the State Health Benefits Program, and the School Employees’ Health Benefits Program (Programs), are now prohibited from imposing any restrictions on the location or setting used by a health care provider to provide services using telemedicine and telehealth, or on the location or setting of where the patient is located when receiving services using telemedicine and telehealth, so long as the services provided using telemedicine and telehealth meet the same standard of care as if the services were provided in person. Further, such Programs are now prohibited from restricting the ability of a provider to use any electronic or technological platform to provide services using telemedicine or telehealth, provided that the platform allows the provider to meet the same standard of care as would be provided if the services were provided in person.

C. Bill to Prohibit State Health Care Boards from Granting Licenses to Sex Offenders Awaits Governor Murphy’s Signature

On December 20, 2021, the New Jersey Assembly passed Bill S3494 which, if signed into law, will prohibit New Jersey professional licensing boards from granting licenses to individuals convicted of certain offenses, including certain sex offenses. The New Jersey Senate had previously passed the Bill on June 3, 2021, and it now awaits Governor Murphy’s signature. The Bill was introduced after the State Board of Chiropractic Examiners in February 2021 reinstated the license of a chiropractor who is a registered sex offender in Florida and is on lifetime parole. The Bill would require that all New Jersey State agencies that license and regulate any health care profession or occupation must deny an initial license, certification or registration, or a renewal, reactivation, or reinstatement of a license, certification, or registration, if the review of an individual’s criminal history records or records with the National Practitioner Data Bank demonstrate that the individual has been convicted of certain offenses, including sexual assault, criminal sexual contact or lewdness, endangering the welfare of a child, attempting to lure or entice a child, or equivalent offenses in another jurisdiction.
D. **Bill Introduced to Limit Fees Charged to Patients for Medical Records**

On December 6, 2021, Bill S4233 was introduced in the New Jersey Senate to limit fees charged to patients and authorized third parties for copies of medical and billing records. An identical bill was introduced in the New Jersey Assembly on December 13, 2021. The Bill would limit fees charged to patients, patients’ legally authorized representatives, and other authorized third parties by hospitals and health care professionals for electronic or paper copies of medical or billing records. Total costs for copies of a medical record, whether the record is stored electronically, on microfilm or microfiche, or paper, would be capped at $50, inclusive of any additional administrative fees charged by the hospital or health care professional for reproducing the requested records. Presently, regulations of the New Jersey State Board of Medical Examiners limit the fee for such records to $100, but the regulations are generally pre-empted by HIPAA’s “reasonable, cost-based fee” requirements. The Bill also would prohibit hospitals and health care professionals from assessing a fee for copies of a patient’s billing record if the record is requested by the patient, the patient’s legally authorized representative, or an authorized third party.

E. **NJ BME Proposes New Rule for Radiologist Assistants**

On December 6, 2021, the New Jersey State Board of Medical Examiners (BME) published a proposed rule to set forth procedures the BME believes are appropriate for licensed radiologist assistants (RAs) to perform, as well as the level of supervision licensed radiologists must provide when RAs are performing such procedures and other related tasks. Highlights of the proposed rule include the following:

- Certain fluoroscopic procedures should not be performed by RAs, as these procedures require either specialized education or the experience of a physician
- Certain tasks must be performed by an RA under the direct supervision, general supervision, or personal supervision of a radiologist:
  - Direct supervision requires a radiologist to be on-site (present in the office suite or department) and be immediately available to provide assistance and direction, but does not require the radiologist to be present in the room when a procedure is performed
  - General supervision means that a procedure is performed under a radiologist’s direction and control, but does not require a radiologist’s presence on-site when a procedure is performed
  - Personal supervision requires a radiologist to be present in the room when a procedure is performed
- Certain tasks may be delegated to an RA, provided that certain conditions are met, including:
  - The radiologist or other licensed physician in the practice or facility has personally certified and documented the RA’s training and ability to perform the task
  - The radiologist is responsible for choosing and ordering pharmaceuticals and contrast materials and for determining the dosage and route of administration
For pediatric patients, the radiologist has experience in the performance of the pertinent procedures with such patients, and

- The radiologist and RA each has current certification in Advanced Cardiovascular Life Support

- If a radiologist seeks to direct an RA to perform certain delineated procedures (lower extremity venography, non-tunneled venous central line placement in the femoral vein, venous catheter placement for dialysis, breast needle localization, and ductogram), the radiologist must provide written notification to the BME and receive written notification from the BME that it has reviewed the submitted information.

Comments to the proposed rule must be submitted by February 4, 2022.

### FEDERAL DEVELOPMENTS

#### A. CMS Enforcing COVID-19 Vaccine Mandate in States Not Affected by Injunctions

On December 28, 2021, CMS published updated information, in the form of a document titled External FAQ, about the CMS COVID-19 vaccine mandate (Interim Final Rule) and the status of the litigation regarding the same. In short, in those states not affected by the injunctions issued in the litigation, including New Jersey, CMS has announced that it will exercise its enforcement authority and advises that “the rule will be implemented and enforced on the following modified timeline: the deadline for Phase 1 implementation is January 27, 2022, and the deadline for Phase 2 implementation is February 28, 2022.”

As of December 15, 2021, the following states were affected by the injunctions imposed by Federal Circuit Courts, which stayed the Interim Final Rule: Alabama, Alaska, Arizona, Arkansas, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, West Virginia, and Wyoming. Accordingly, Medicare- and Medicaid-certified providers in those states were not required to comply with the Interim Final Rule, and CMS directed its surveyors not to investigate compliance with the Interim Final Rule in facilities located in those states. However, on Thursday, January 14, 2022, the U.S. Supreme Court lifted the injunctions that had been imposed by the Federal Circuit Courts, which allows CMS to proceed with enforcement in those states as well.

Medicare- and Medicaid-certified providers covered by the Interim Final Rule must act quickly to put into place policies and procedures to comply with the mandate.

#### B. The U.S. Supreme Court Hears Arguments on the OSHA COVID-19 ETS

On November 5, 2021, the Federal Occupational Health and Safety Agency (OSHA) issued an Emergency Temporary Standard (ETS) relating to the vaccine mandate for employers with 100 or more employees to ensure each of their workers is either fully vaccinated or tests for COVID-19 on at least a weekly basis. However, on November 12, 2021, OSHA announced that it had suspended all activities related to the implementation and enforcement of the ETS. The
announcement was a result of the Fifth Circuit Court of Appeals entering a stay barring OSHA from taking any steps to implement and enforce the ETS.

On December 17, 2021, the Sixth Circuit Court of Appeals dissolved the Fifth Circuit’s stay and allowed OSHA to implement the ETS. Thereafter, several petitions to the U.S. Supreme Court were filed seeking to reinstate the stay. On January 7, 2022, the U.S. Supreme Court heard oral arguments and on January 14, 2022, the U.S. Supreme Court reinstated the stay of the ETS.

C. Physician Owner of ASC May Profit From Employed CRNA’s Services at ASC

On November 15, 2021, the Office of Inspector General (OIG) of the Department of Health & Human Services issued an Advisory Opinion No. 21-15 determining that a pain management practice solely owned by a physician and the ambulatory surgery center (ASC) at which the physician is a majority owner may profit from anesthesia services performed by the practice’s employed certified registered nurse anesthetist (CRNA) in the practice office and at the ASC. The OIG concluded that it would not impose sanctions under the federal anti-kickback statute relating to the proposed arrangement.

Under the federal anti-kickback statute, it is a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in exchange for, referrals reimbursable under a federal health care program. “Remuneration” includes the transfer of anything of value, directly or indirectly, in cash or in kind. The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to induce referrals. The statute and its regulations provide safe harbors, or exceptions, that set forth specific arrangements that do not violate the law. One safe harbor applies to compensation paid to a bona fide employee.

Under the arrangement described in the advisory opinion, the pain management practice pays a salary to the employed CRNA, who provides anesthesia services in the practice’s office and at the ASC. Under the CRNA’s employment agreement, the CRNA reassigned to the practice the right to receive reimbursement for the separately-billable anesthesia services performed by the CRNA, whether in the medical office or in the ASC. The practice bills for all of the CRNA’s anesthesia services provided in both settings. The practice also assumes responsibility for the CRNA’s performance of anesthesia services. The OIG determined that, because the CRNA is a bona fide employee of the practice, the salary to the employee is not a kickback. The OIG further found that although the reassignment of benefits flows from the employee to the employer, and technically is not protected by the anti-kickback statute’s employee safe harbor, the arrangement is not a kickback scheme, because salaries to bona fide employees in exchange for reassignment of benefits are (i) a common practice in the health care industry, and (ii) are explicitly authorized by the Medicare program.

D. HHS OCR and USAO Settle Disability Discrimination Case with Medical Center

The U.S. Department of Health & Human Services, Office for Civil Rights (OCR), along with the U.S. Department of Justice through the U.S. Attorney’s Office for the District of Massachusetts (DOJ), entered into a Voluntary Resolution Agreement with Baystate Medical Center (Baystate) arising from a complaint on behalf of an individual (Complainant) who is deaf and utilizes
American Sign Language (ASL) to communicate. The Complainant alleged that Baystate failed to furnish appropriate auxiliary aids and services necessary to effectively communicate with her during her hospitalization, in violation of Title III of the Americans with Disabilities Act (ADA) and its implementing regulations. The Complainant also alleged that, despite requesting a qualified ASL interpreter before her scheduled arrival to induce labor, Baystate failed to take appropriate steps to ensure that its communications with her during labor and childbirth were effective.

The OCR investigated the Complainant’s allegations, in partnership with the DOJ, and reviewed Baystate’s policies and procedures for effective communications with individuals who are deaf or hard of hearing, as required under Section III of the ADA, Section 504 of the Rehabilitation Act of 1973 and Section 1557 of the Affordable Care Act. During the course of the investigation, the DOJ learned of a second aggrieved party who made similar allegations.

In settlement of the allegations, Baystate agreed, among other things, to (i) pay monetary compensation to each of the Complainant and the second complainant, (ii) review and revise its policies concerning effective communications with patients who are deaf or hard of hearing and the provision of auxiliary aids, and (iii) provide training on the provision of auxiliary aids and services.